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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,193	08/30/2005	Mitsuomi Hirashima	2005_1172A	9834

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EXAMINER	
YAO, LEI	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,193	HIRASHIMA ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a pharmaceutical or veterinary drug, comprising ONE member from a-e listed in claim 1 and ONE drug for treating a specific disease (require further election).

Group II, claim(s) 10, drawn to a cytotoxic drug for tumor cells comprising ONE member from a-e listed in claim 10 (require further election).

Group III, claim(s) 11, drawn to an apoptosis-inducing drug for tumor cells comprising ONE member from a-e listed in claim 11 (require further election).

Group IV, claim(s) 12, drawn to a an apoptosis-inducing drug fro immune cells, including especially activated T cells comprising ONE member from a-e listed in claim 12 (require further election).

Group V, claim(s) 13, drawn to a prophylactic and/or therapeutic agent for disease or pathological conditions caused by activated T cells comprising ONE member from a-e listed in claim13 (require further election).

Group VI, claim14, drawn to a galectin-9 binding factor (require further election).

Group VII, claim(s) 15, drawn to method (technique) for controlling the activity of galectin 9 comprising interaction between galectin 9-binding factor and galectin (require further election).

Further **restriction** is required under 35 U.S.C. 121:

If applicants elect group I set forth above, further elect group A and B.
If applicants elect any group from II-IV set forth above, further elect group A.
If applicants elect group VI or VII set forth above, further elect group C.

A. Elect ONE from the following:

Galectin 9/analogs;
polynucleotide coding for galectin 9;
inducing factors for production and/or release of galectin 9;
anti-galectin 9-receptor antibodies;
antibodies against a galectin 9-binding saccharide.

B. Elect One from the following:

anti-tumor agents
anti-allergic agents,
immunosuppressant
drug for auto-immune disease
anti-inflammatory agents
active components for adrenocortical steroid hormone alternatives.

C. One molecule listed in claim 14.

This application is an internationally filed application filed under 35 U.S.C. 371 and is subject to the rules discussed under MPEP § 1850 (see the last paragraph under MPEP § 803.04, which references the appropriate section for internationally filed applications). Under Markush practice for international applications, the following criteria are required:

(A) the alternatives have a common property or activity and (B) a common core structure is present; or

(C) in cases where the core structure cannot be the unifying criteria, all alternatives must belong to the same recognized class of chemical compounds, that is, that the same result will be achieved when one member of the Markush group is substituted for another.

In the instant case, each molecule has a unique structure/sequence and function and they do not share a common core structure or activities. Therefore, the molecules do not meet the criteria for (A) and (B). Also; molecules do not meet criteria (C) because the same result is not achieved when galectin 9 used for treating cancer is substituted for antibody to galectin 9 or treating cancer patient with an anticancer reagent is substituted for anti-allergic agents. Since the instant molecules or drugs do not share the same or corresponding special technical feature under the specific criteria for Markush practice, the molecules or drugs lack unity of invention and are not considered alternative species to one another. Therefore, applicant's proposed species election would be improper.

In order to be fully responsive, Applicant must elect one from Groups I-VII, one from Group A-C even though the requirement is traversed. Applicant is advised that neither I–VII, nor A-C is species election requirements; rather, each of I-VII and A-C is a restriction requirement.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as group I-VII do not related to s single general invention concept because the lack the same or corresponding special technical feature. The technical feature of group I-VI is drawn to a pharmaceutical or a drug comprising an galectin 9, which is shown by Ni et al., (US Patent, 60279916, issue 2000) to lack novelty or inventive step. Ni et al., teach that Galectin 9 as a drug for diagnosing and treating diseases comprising cancer, autoimmune, inflammatory, allergic disease (col 16, last para). Therefore, the invention Groups I-VI do not make a contribution over the prior art. Because the galectin 9 is known in the art, the technical feature of the Groups I-VI is not a special technical feature, the unity of invention (Group I-VII) is lacking.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitation of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitation of an allowable product claim for that process invention to be rejoined.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution to require the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

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